

ATTACHMENT 3

Comments Received at Public Meeting

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Comment A. There should be different guidance for different types of rules.

Response. The NRC disagrees with this comment as the current Regulatory Analysis Guidelines consistently present broad policy positions that are designed to be applicable to all regulatory initiatives that are subject to regulatory analysis requirements. Further, the NRC believes that having different guidance for different types of rules may unnecessarily complicate the regulatory analysis process. In addition, it is possible that some rules may fall into more than one category (such as a rule that is both risk-informed and a backfit), in which case it would be unclear which criteria to use when analyzing a rule.

Comment B. For rules that provide risk-informed voluntary alternatives to current regulations, an individual requirement should have to be cost-justified and integral to the purpose of the rule rather than cost-justified or integral to the purpose of the rule.

Response. The NRC maintains that if an individual requirement is integral to the purpose of the rule, then that alone is a sufficient basis for its inclusion, and in fact, a decision on its inclusion or exclusion is not discretionary. However, the NRC finds that if a requirement is not deemed integral, it should be included if it is cost-justified. This alone is a sufficient basis because cost-benefit methodology directs one to select the alternative with the largest net benefit. This is clearly stated in OMB guidance and guidance contained elsewhere in NRC's Regulatory Analysis Guidelines. Clearly, if an individual requirement is cost-justified, its inclusion will result in a larger net benefit than an alternative that excludes the individual requirement. (Note, the proposed criteria no longer contain the phrase "integral to the purpose of the rule," but rather use the word "necessary" and provide examples of when a requirement may be deemed necessary.)

Comment C. How does a risk-informed alternative rule proceed if some element of the rule is found to be a candidate for backfitting?

Response. The revised criteria state that in some cases an increased requirement may be justifiable under the criteria of 10 CFR 50.109(a)(3) (i.e., it may be cost-justified and provide a substantial increase in the overall protection of the public health and safety or the common defense and security). If so, the requirement should be considered for imposition as a backfit (where it would affect all plants to which it applies) rather than merely being included in a voluntary alternative rule (where it would affect only those plants where the voluntary alternative is adopted). The revised criteria do not, however, specify whether or how a risk-informed alternative rule will proceed if one of its elements is being considered for backfitting. It is expected that such decisions will be made on a case by case basis.

Comment D. Objectives must be clearly stated by the NRC staff and approved by the Commission.

Response. The NRC agrees that the objectives of a rule should be clearly stated. The revised criteria indicate that the objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule. The objectives, along with other parts of the *Federal Register* notice, are approved by the Commission if the rule is of the type that requires Commission approval, as is usually the case for the rules of interest in this discussion.

Comment E. How will the new guidelines be implemented?

Response. The NRC staff's current plans are to recommend proposed criteria to the Commission. If the Commission approves the recommendation, the staff then plans to publish these criteria for public comment. After considering these comments, the NRC staff will develop and issue final criteria provided there are no significant changes due to public comments. However, if there are significant changes to the criteria, the staff will submit the final recommended criteria for the approval of the Commission. The NRC plans to incorporate the criteria into a revision to NUREG/BR-0058. There may be other changes to NUREG/BR-0058, beyond incorporation of these criteria, that will also be addressed in the revision.

Comment F. Backfit Rule language seems to focus on individual requirements, but the Executive Order mandating regulatory analyses is focused on an aggregate approach.

Response. The NRC believes that an approach of analyzing individual components of a rule is consistent with the regulatory philosophy of Executive Order 12866 that agencies should select regulatory approaches that maximize net benefits. The NRC does not believe that Executive Order 12866 requires either an individual or aggregate approach.

Comment G. There is a concern that the new guidelines will erode the standard of 10 CFR 50.109(a)(3), which for certain backfits requires “a substantial increase in the overall protection of the public health and safety or the common defense and security.

Response. The NRC does not believe that the criteria would erode the “substantial increase” standard. The proposed criteria do not require that each individual rule requirement which must be separately analyzed under the proposed guidelines meet the “substantial increase” standard.

Comment H. Instead of allowing the analyst to rely on his or her judgment to determine the individual requirements that may be included in a draft regulatory analysis or backfit analysis at the proposed rule stage, each discrete new requirement should be analyzed individually.

Response. While the NRC agrees that it often makes sense to divide a rule into discrete elements in performing regulatory analyses—and this is how the NRC generally performs these analyses—the NRC does not believe that there should be a general requirement for a separate analysis of each individual requirement of a rule. This could lead to unnecessary complexities and there would not be a reasonable expectation of added value because there is not a history of including inappropriate individual requirements. However, the public may comment on the appropriate level of disaggregation in any public comment opportunity provided in accordance with standard NRC procedures.

Comment I. There should be more specific guidance with regard to the analyst relying on his or her judgment at the proposed rule stage.

Response. In response to this comment, the NRC has added more guidance regarding the appropriate level of disaggregation in an analysis. Specifically, this guidance states that a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality, and that a more detailed disaggregation would only be appropriate if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results.

Comment J. The analyst's judgment should be explained.

Response. Requiring an explanation of why it is permissible to include each individual element or sub-element of the rule would be essentially similar to requiring individual analyses.

Comment K. With regard to the four conditions that constitute “integral to the purpose of the rule,” how are they related? Are all four needed? Especially “not separable.”

Response. The revised criteria do not make use of the term “integral to the purpose of the rule” and the four conditions are not used.

Comment L. How is “defense-in-depth” related to the four conditions that constitute “integral to the purpose of the rule”?

Response. The four conditions are no longer referenced in the proposed criteria.

Comment M. After the end of a public comment period, how can public input be made in the process when changes occur?

Response. Late comments will be considered when time permits. Sometimes a public meeting such as an ACRS briefing or a Commission briefing provides an opportunity to find out what is happening and/or make comments. If an OMB clearance is needed, there is an additional opportunity to comment.

Comment N. We are concerned when we provide data, it will be used in proper context.

Response. The NRC agrees that data provided should be used in proper context.